1 FILED IN THE U.S. DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON 2 Apr 21, 2023 SEAN F. McAVOY, CLERK 3 UNITED STATES DISTRICT COURT EASTERN DISTRICT OF WASHINGTON 4 5 STATE OF WASHINGTON, STATE OF OREGON, STATE OF ARIZONA, NO. 1:23-CV-3026-TOR 6 STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF ORDER DENYING MOTION TO DELAWARE, STATE OF ILLINOIS, 7 **INTERVENE** ATTORNEY GENERAL OF MICHIGAN, STATE OF NEVADA, 8 STATE OF NEW MEXICO, STATE 9 OF RHODE ISLAND, STATE OF VERMONT, DISTRICT OF COLUMBIA, STATE OF HAWAII, 10 STATE OF MAINE, STATE OF 11 MARYLAND, STATE OF MINNESOTA, and 12 COMMONWEALTH OF PENNSYVLANIA, 13 Plaintiffs, 14 v. 15 UNITED STATES FOOD AND 16 DRUG ADMINISTRATION, ROBERT M. CALIFF, in his official 17 capacity as Commissioner of Food and Drugs, UNITED STATES 18 DEPARTMENT OF HEALTH AND HUMAN SERVICES, and XAVIER BECERRA, in his official capacity as 19 Secretary of the Department of Health 20 and Human Services,

Defendants.

BEFORE THE COURT are Proposed State Plaintiff-Intervenors' Motion to Intervene (ECF No. 76), Motion to Appear Pro Hac Vice re Attorney: Joshua N. Turner (ECF No. 77), Motion to Appear Pro Hac Vice re Attorney: Peter M. Torstensen, Jr. (ECF No. 79), Motion to Appear Pro Hac Vice re Attorney: Thomas T. Hydrick (ECF No. 85), Motion to Appear Pro Hac Vice re Attorney: Eric H. Wessan (ECF No. 87), Motion to Appear Pro Hac Vice re Attorney: Leif A. Olson (ECF No. 88), and Motion to Appear Pro Hac Vice re Attorney: Christopher A. Bates (ECF No. 89). These motions were submitted for consideration without oral argument. The Court has reviewed the record and files herein, the completed briefing, and is fully informed.

## **BACKGROUND**

On March 3, 2023, Plaintiffs filed an Amended Complaint, seeking the following relief: (1) "Declare ... that mifepristone is safe and effective and that Defendants' approval of mifepristone is lawful and valid;" (2) "Declare ... that the mifepristone REMS violated the Administrative Procedures Act;" (3) "Declare ... that the mifepristone REMS violated the United States Constitution;" (4) "Enjoin Defendants ... from enforcing or applying the mifepristone REMS;" (5) "Enjoin Defendants ... from taking any action to remove mifepristone from the market or

reduce its availability;" and (6) "Award such additional relief as the interests of justice may require." ECF No. 35 at 90.

On March 30, 2023, the Proposed State Plaintiff-Intervenors ("State Intervenors") filed the present Motion to Intervene, seeking to intervene as a matter of right, or alternatively, through permissive intervention. See ECF No. 76. State Intervenors seek to file a Complaint, claiming the following relief: (1) "Adjudge and declare ... that the FDA's final agency action on January 3, 2023 modifying the mifepristone REMS violated the notice-and-comment requirements under the Administrative Procedure Act[;]" (2) "Adjudge and declare ... that the FDA's final agency action on January 3, 2023 modifying the mifepristone REMS is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under the Administrative Procedure Act;" (3) "Adjudge and declare ... that the FDA's final agency action on January 3, 2023 modifying the mifepristone REMS exceeds the statutory authority granted to the FDA under the FDCA;" (4) "Enjoin Defendants ... from enforcing or applying the January 3, 2023 mifepristone REMS;" (5) "Vacate the FDA's January 3, 2023 final agency action;" and (6) "Award [State Intervenors] such additional relief as the Court may deem just, proper, and necessary, including their attorneys' fees and costs associated with this litigation." ECF No. 76-1 at 20.

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On April 7, 2023, this Court preliminarily enjoined Defendants from altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy under 21 U.S.C. § 355-1 in Plaintiff States and the District of Columbia. ECF Nos. 80, 91.

Following this Court's preliminary injunction, the State Intervenors filed a Motion to Expedite the Court's consideration of the Motion to Intervene, which the Court granted. ECF Nos. 90, 96. Both parties oppose the Motion to Intervene. ECF Nos. 92, 93. State Intervenors timely filed a reply. ECF No. 103.

## **DISCUSSION**

## I. Intervention as of Right

"On timely motion, the court must permit anyone to intervene who... claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2). Thus, the applicant seeking to intervene must show (1) timeliness, (2) a significantly protectable interest relating to the subject of the action, (3) that interest is subject to impairment by disposition of the case, and (4) the interest is not adequately represented by the parties. *W. Watersheds Project v. Haaland*, 22 F.4th 828, 835 (9th Cir. 2022). The requirements are interpreted broadly in favor of intervention and review "is guided"

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primarily by practical considerations, not technical distinctions." *Id.* (citation omitted). A failure to meet any element is fatal to mandatory intervention. *Perry v. Proposition 8 Official Proponents*, 587 F.3d 947, 950 (9th Cir. 2009).

"Whether an applicant for intervention as of right demonstrates sufficient interest in an action is a 'practical, threshold inquiry,' and '[n]o specific legal or equitable interest need be established." *Citizens for Balanced Use v. Montana Wilderness Ass'n*, 647 F.3d 893, 897 (9th Cir. 2011) (citation omitted). The interest must be "protectable under some law" with a "relationship between the legally protected interest and the claims at issue." *Id.* A relationship exists "if the resolution of the plaintiff's claims actually will affect the applicant." *Donnelly v. Glickman*, 159 F.3d 405, 410 (9th Cir. 1998) (citation omitted).

State Intervenors contend they have "significantly protectable interests related to the FDA's decision to modify mifepristone's REMS." ECF No. 76 at 4. Specifically, (1) "eliminating mifepristone's in-person dispensing requirement will harm women residents of the State Intervenors"; (2) "FDA's action .... undermines the State Intervenors' ability to enforce their laws" and (3) "FDA's action violates the Administrative Procedures Act[.]" ECF No. 76 at 4–5.

It is not enough that both groups assert APA claims against the FDA relating to the 2023 Mifepristone REMS Program. *Donnelly v. Glickman*, 159 F.3d 405, 409 (9th Cir. 1998). As a practical matter, State Intervenors' claims are not at

issue in this case. *See* ECF No. 76-1. State Intervenors challenge the 2023 REMS on the grounds that the in-person dispensing requirement should not have been removed. *See id.* The in-person dispensing requirement is not at issue in this case, and will neither be eliminated nor reinstated as a result of this litigation.

Moreover, this case will not impair State Intervenors' ability to enforce their own state laws regulating medication abortion. *See Am. Coll. Of Obstetricians & Gynecologists v. United States Food & Drug Admin.*, 467 F. Supp. 3d 282, 289 (D. Md. 2020) ("[T]he resolution of this case will not eliminate any state's ability to continue to regulate medication abortion, as they choose, above and beyond the FDA's requirements.").

Therefore, resolution of this case will not affect State Intervenors' claims that FDA should have more restrictive limitations than the 2023 REMS nor will this litigation impede State Intervenors' own laws. State Intervenors do not have a "significant protectable interest" that has a sufficient relationship to the claims at issue in this case. On this ground alone, intervention as a matter of right fails.

## **II.** Permissive Intervention

"On timely motion, the court may permit anyone to intervene who... has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). Even if satisfied, district courts have discretion to deny permissive intervention. *Cooper v. Newsom*, 13 F.4th 857, 868 (9th Cir.

2021), cert. denied sub nom. San Bernardino Cnty. Dist. Att'y v. Cooper, 143 S. Ct. 287 (2022).

State Intervenors assert their "APA claims are grounded in the same facts and the same laws as the existing Plaintiffs' action." ECF No. 76 at 7. However, in practical application, this is not true. The question in this case is whether the January 2023 REMS violates the APA by imposing patient agreement form, provider certification, and pharmacy certification requirements. *See* ECF No. 35. The question State Intervenors pose is whether the January 2023 REMS violates the APA by *not* imposing an in-person dispensing requirement. *See* ECF No. 76-1. As a result, the Court finds there is no common question of law or fact within the meaning of Rule 24(b). Moreover, the addition of State Intervenors who allege claims and relief not at issue would cause additional delay in this complex litigation. *Cooper*, 13 F.4th at 868.

As a result, the Court declines to permit State Intervenors to intervene in this case. Fed. R. Civ. P. 24(b). As the above findings are dispositive, the Court declines to address the remaining arguments. State Intervenors' Motion is denied.

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# ACCORDINGLY, IT IS HEREBY ORDERED:

- Proposed State Plaintiff-Intervenors' Motion to Intervene (ECF No. 76) is **DENIED**.
- 2. Motion to Appear Pro Hac Vice re Attorney: Joshua N. Turner (ECF No. 77) is **GRANTED**.
- 3. Motion to Appear Pro Hac Vice re Attorney: Peter M. Torstensen, Jr. (ECF No. 79) is **GRANTED**.
- 4. Motion to Appear Pro Hac Vice re Attorney: Thomas T. Hydrick (ECF No. 85) is **GRANTED**.
- 5. Motion to Appear Pro Hac Vice re Attorney: Eric H. Wessan (ECF No. 87) is **GRANTED**.
- Motion to Appear Pro Hac Vice re Attorney: Leif A. Olson (ECF No. 88) is GRANTED.
- 7. Motion to Appear Pro Hac Vice re Attorney: Christopher A. Bates (ECF No. 89) is **GRANTED**.

The District Court Executive is directed to enter this Order and furnish copies to counsel.

DATED April 21, 2023.



ORDER DENYING MOTION TO INTERVENE ~ 8